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(54) Title: SKIN BARRIER ENHANCING ABSORBENT TISSUES

(57) Abstract

A superior skin barrier enhancing tissue product, such as facial tissue, bath tissue or paper towels and the like, can be made by applying, on the surface(s) of the tissue, a lipid-enriched melted hydrophilic composition comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty alcohol ($C_{14} - C_{30}$ or greater), humectant, an oil-in-water emulsifying surfactant having an HLB range greater than 7, or β -sterol, and a natural fat or oil, and thereafter resolidifying the composition to form a distribution of solid composition on the surface(s) of the tissue.

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Skin Barrier Enhancing Absorbent Tissues

Field of the Invention

The present invention relates to the inclusion of a lipid-enriched hydrophilic lotion on absorbent tissue products, such as facial tissue, bath tissue, paper towels, and the like. More particularly, the present invention relates to improving skin health via enhancement of skin barrier function by the delivery of lipids and humectants from a hydrophilic lotion from said absorbent tissue products to the skin.

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Background of the Invention

The stratum corneum is the outer-most layer of the skin and is responsible for regulating skin water levels and functioning as a barrier against chemicals and other stressors found in the environment. The complex arrangement of lipids in the intercellular space of the stratum corneum is responsible for the establishment of normal barrier function. Multi-layered structures of cholesterol, ceramides, and fatty acids, as well as some other minor lipids, provide the major barrier to the transport of hydrophilic substances into the or through the skin. The link between the barrier function and skin 20 health is apparent from the skin inflammation caused by lipid extraction from the skin.

Skin barrier can be damaged due to a number of mechanisms. Physical abrasion, for example caused by the repeated rubbing of absorbent tissue products on the skin, strips away layers of the skin and thus damages skin barrier. Biological fluids, such as urine, feces, nasal and vaginal secretions, may contain a variety of components that can damage skin barrier. Examples of these components include proteases, lipases, bile acids, and fatty acids. Once the skin barrier is compromised, these components, in addition to other constituents of biological fluids, can initiate or exacerbate skin inflammation.

Excessive hydration also has a negative impact on skin barrier. The hydration level of diapered skin, for example, may reach between five to ten times that of undiapered skin. Frequent contact of diapered skin with fluids such as nasal secretion

may also contribute to increased skin hydration. Increased skin hydration disrupts skin lipid organization in the stratum corneum. This disruption may increase-the skin permeability irritants, thus increasing the risk of skin inflammation.

Typically, topically applied barrier creams, lotions and ointments are used to provide an artificial hydrophobic barrier on the skin. These products typically contain mineral oils, petrolatum and silicones that are heavy, greasy to the touch and are typically used to treat, rather than prevent skin irritation. In some instances, such as individuals suffering from sore, irritated noses during a cold, these products are avoided due to their poor cosmetic value to the consumer.

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Absorbent tissue products such as facial tissue and bath tissue have been used to absorb body fluids and leave the skin dry. Absorbent tissue, in addition to absorbing fluids, however, also abrade the skin during use and frequently do not leave the skin completely dry and free of the body fluid the tissue is trying to absorb. During frequent nose-blowing or perianal wiping, for example, the skin can become so abraded as to appear red and be sore to the touch. To reduce skin abrasion, tissue additive formulations can be applied to the tissue such that, in use, the additive formulation either provides lubricity causing the tissue to glide across the surface of the skin, or leaves the tissue and is deposited on the skin.

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Once deposited on the skin, these additive formulations provide a skin benefit by occluding the skin. Thus, these formulations provide a short-term benefit by providing an artificial barrier, even though the underlying stratum corneum is still damaged.

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To date, these formulations have been wax-based semi-solids or solids at room temperature. Since these formulations are lipophilic, it is sometimes difficult to incorporate hydrophilic or water soluble surfactants, cosmetic materials or other active ingredients that can provide a skin health benefit.

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Thus, there is a need for a formulation that is basically hydrophilic that can be applied to a tissue which will remain readily available for transfer to the user's skin to protect, maintain, and aid recovery of skin barrier function and thus protect the skin from irritation, inflammation, and redness in an efficient cost-effective manner.

Thus, what is further needed in the art is formulation chemistry that, when applied from an absorbent tissue, enhances the skin's barrier function while minimizing or eliminating the physical damage caused by the rubbing of the said absorbent tissue on the skin surface.

Summary of the Invention

It has now been discovered that a skin barrier enhancing tissue product can be made applying, on the surface(s) of the tissue, a lipid-enriched melted hydrophilic composition comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty alcohol (C₁₄ - C₃₀ or greater), a humectant, an oil-in-water emulsifying surfactant having an HLB range greater than 7, a sterol, and a natural fat or oil, and thereafter resolidifying the composition to form a distribution, preferably a uniform distribution, of solid deposits on the surface(s) of the tissue. Because the hydrophilic composition is a solid at room temperature and rapidly solidifies after deposition, it has less tendency to penetrate and migrate into the sheet. Compared to tissues treated with liquid formulations, this leaves a greater percentage of the added anhydrous solid lotion composition on the surface of the tissue where it can contact and transfer to the user's skin to provide a benefit. Furthermore, a lower add-on amount can be used to deliver the same benefit at a lower cost because of the efficient placement of the composition substantially at the surface of the product.

Hence, in one aspect, the present invention is a hydrophilic composition comprising from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol (preferably having a molecular weight of about 720 or greater), from about 1 to about 30 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 30 weight percent of humectant, from about 1 to about 20 weight percent emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol or sterol derivative, and from about 0.1 to about 30 weight percent of natural fats or oils. The hydrophilic composition may have a melting point from about 30 °C. to about 100 °C. The composition may also have a penetration hardness of from about 5 millimeters to 360 millimeters.

In another aspect, the invention resides in a tissue product wherein one or both of the outer surfaces of the product have solidified deposits of a composition comprising from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol (preferably having a molecular weight of about 720 or greater), from about 1 to about 30 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 30 weight percent of humectant, from about 1 to about 20 weight percent emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol or sterol derivative, and from about 0.1 to about 30 weight percent of natural fats or oils. The hydrophilic composition may have a melting point from about 30°C, to about 100°C. The composition may also have a penetration hardness of from about 5 millimeters to 360 millimeters.

In another aspect, the present invention is a method of making a soft tissue or towel product that enhances skin barrier comprising: (a) heating a hydrophilic composition comprising a hydrophilic solvent, high molecular weight polyethylene glycol, a fatty alcohol, a humectant, an emulsifying surfactant having an HLB range greater than 7, a sterol or sterol derivative, and a natural fat or oil to a temperature above the melting point of the composition, causing the composition to melt; (b) uniformly applying the melted composition to one or both surfaces of the tissue web; and, (c) resolidifying the melted composition. The hydrophilic composition may have a melting point of from about 30 °C. to about 100 °C.

Detailed Description of the Invention

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One embodiment of the present invention is a tissue or towel product having two outer surfaces. One or both outer surfaces of the product have solidified deposits of a composition that enhances skin barrier. The composition may comprise from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater, from about 1 to about 30 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 30 weight percent of humectant, from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent sterol and sterol derivative, and from about 0.1 to about 30 weight percent of natural fats or oils.

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The composition may have a melting point from about 30° C to about 100 °C. The composition may have a penetration hardness of from about 5 millimeters to about 360 millimeters. The add-on amount of the composition may be from about 0.5 to about 30 weight percent based on the weight of said product. The add-on amount of the composition may also be expressed as from about 0.1 grams per meter squared (g/m²) to about 30 g/m² of the tissue or towel product, and more preferably from about 0.5 g/m² to about 25 g/m².

The hydrophilic solvent used in the composition may include water, propylene glycol, a low molecular weight polyethylene glycol, glycerin, or hydrogenated starch hydrolysate. The fatty alcohol used in the composition may include cetyl alcohol, stearyl alcohol, arachidyl alcohol, or behenyl alcohol. The molecular weight of said high molecular weight polyethylene glycol used in the composition may include from about 720 to about 1,840,000 daltons, more specifically from about 1,400 to about 440,000 daltons. The molecular weight of said high molecular weight polyethylene glycol used in the composition may include polyethylene glycol 1,400, polyethylene glycol 8,000, or polyethylene glycol 10,000. The humectant used in the composition may include glycerin, sorbitol, or hydrogenated starch hydrolysate. The surfactant used in the composition may include glyceryl stearate SE, glycol stearate SE, or emulsifying wax NF. The sterol or sterol derivative used in the composition may include soy sterol, cholesterol, or lanasterol. The natural fat or oil used in the composition may include sunflower oil, borage oil, or avocado oil.

Another embodiment of the present invention is a method of making a tissue or towel material having an outer surface comprising: (a) heating a composition that enhances skin barrier comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty alcohol, a humectant, an oil-in-water emulsifying surfactant having an HLB range greater than 7, a natural fat or oil, and a sterol or sterol derivative, to a temperature above the melting point of the composition, causing the composition to melt; (b) applying the melted composition to the outer surface of a liner or tissue material web; and (c) resolidifying the melted composition.

The composition may have a melting point of from about 30 °C to about 100 °C. The resolidified composition may have a penetration hardness of from about 5 to about 360 millimeters. The melted composition may be applied by printing.

Another embodiment of the present invention is a skin barrier enhancing composition comprising from about 5 to about 90 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater, from about 1 to about 25 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 10 weight percent of humectant, from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol and sterol derivative.

The composition may have a melting point from about 30 °C. to about 100 °C. The resolidified composition may have a penetration hardness of from about 5 to about 360 millimeters.

The hydrophilic solvent of the composition may be selected from the group consisting of: water, propylene glycol, low molecular weight polyethylene glycol, glycerin, sorbitol, hydrogenated starch hydrolysate, silicone glycol, and the like, as well as mixtures thereof. The fatty alcohol of the composition may be selected from the group consisting of: cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol, and the like, as well as mixtures thereof. The high molecular weight polyethylene glycol of the composition may be selected from the group consisting of: polyethylene glycols having a average molecular weight greater than 720 daltons.

The humectant of the composition may be selected from the group consisting of: glycerin, propylene glycol, sorbitol, polyethylene glycol, hydrogenated starch hydrolysates, sodium PCA, potassium PCA, sodium lactate, and the like, as well as mixtures thereof. The surfactant of the composition may be selected from the group consisting of: glyceryl stearate SE, glyceryl stearate, glycol stearate SE, glycol stearate, emulsifying wax NF, and the like, as well as mixtures thereof. The sterol or sterol derivative of the composition may be selected from the group consisting of: β-sterols having a tail on the 17 position and having no polar groups for example cholesterol, sitosterol, stigmasterol, ergosterol, as well as, C₁₀-C₃₀ cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol

acetate, lanasterol, soy sterol, avocado sterols, cholesterol esters, sterol esters, and the like, as well as mixtures thereof.

The natural fat or oil of the composition may be selected from the group consisting
of: avocado oil, apricot oil, babassu oil, borage oil, camellia oil, canola oil, castor oil,
coconut oil, corn oil, cottonseed oil, evening primrose oil, hydrogenated cottonseed oil,
hydrogenated palm kernal oil, maleated soybean oil, meadowfoam oil, palm kernal oil,
phospholipids, rapeseed oil, palmitic acid, rose hip oil, sunflower oil, soybean oil,
derivatives of natural fats or oils (such as stearic acid, linoleic acid, stearyl alcohol, lauryl
alcohol, myristyl alcohol, benenyl alcohol, and the like), and the like, as well as mixtures
thereof.

The amount of the hydrophilic solvent used in the composition may be from about 5 to about 90 weight percent, and more specifically from about 25 to about 75 percent. The amount of said high molecular weight polyethylene glycol used in the composition may be is from about 5 to about 95 weight percent, and more specifically from about 15 to about 50 weight percent.

The amount of said fatty alcohol used in the composition may be from about 1 to about 30 percent. The amount of said surfactant used in the composition may be from about 1 to about 20 percent. The sterol or sterol derivative used in the composition may be from about 0.1 to about 10 percent. The amount of said natural fat or oil used in the composition may be from about 0.1 to about 30 percent.

One embodiment of the composition comprises about 48.2 weight percent propylene glycol, about 20 weight percent polyethylene glycol 8,000, about 20 weight percent stearyl alcohol about 5 weight percent glycerin, about 3 weight percent glyceryl stearate SE, about 0.8 weight percent soy sterol, and about 3 weight percent borage oil.

Another embodiment of the composition comprises about 34 weight percent propylene glycol, about 20 weight percent polyethylene glycol 8,000, about 10 weight percent stearyl alcohol, about 10 weight percent behenyl alcohol about 15 weight percent glycerin, about 5 weight percent propylene glycol oleate SE, about 1 weight percent cholesterol, and about 5 weight percent sunflower oil.

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Another embodiment of the composition comprises about 42.2 weight percent propylene glycol, about 20 weight percent polyethylene glycol 8,000, about 20 weight percent stearyl alcohol, about 5 weight percent glycerin, about 2 weight percent glyceryl stearate SE, about 0.8 weight percent soy sterol, and about 10 weight percent borage oil.

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Another embodiment of the composition comprises about 42.2 weight percent propylene glycol, about 20 weight percent polyethylene glycol 8,000, about 20 weight percent stearyl alcohol, about 5 weight percent glycerin, about 2 weight percent glyceryl stearate SE, about 0.8 weight percent soy sterol, and about 10 weight percent avocado oil.

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Another embodiment of the composition comprises about 42.2 weight percent propylene glycol, about 20 weight percent polyethylene glycol 8,000, about 20 weight percent stearyl alcohol, about 5 weight percent glycerin, about 2 weight percent glyceryl stearate SE, about 0.8 weight percent soy sterol, and about 10 weight percent lanolin oil.

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Another embodiment of the composition comprises about 42.2 weight percent propylene glycol, about 20 weight percent polyethylene glycol 10,000, about 20 weight percent behenyl alcohol, about 5 weight percent glycerin, about 2 weight percent glyceryl stearate SE, about 0.8 weight percent avocadin, and about 10 weight percent sunflower oil.

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Another embodiment of the composition comprises about 32.2 weight percent polyethylene 200, about 20 weight percent polyethylene glycol 1,000, about 30 weight percent behenyl alcohol, about 5 weight percent hydrogenated starch hydrolysate, about 2 weight percent glyceryl stearate SE, about 0.8 weight percent avocadin, and about 10 weight percent avocado oil.

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Another embodiment of the composition comprises about 32.2 weight percent polyethylene 200, about 20 weight percent polyethylene glycol 1,000, about 30 weight percent behenyl alcohol, about 5 weight percent hydrogenated starch hydrolysate, about 2 weight percent glyceryl stearate SE, about 0.8 weight percent avocadin, and about 10 weight percent sunflower oil.

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Another embodiment of the composition comprises about 37 weight percent polyethylene 200, about 20 weight percent polyethylene glycol 8,000, about 10 weight

percent behenyl alcohol, about 10 weight percent stearyl alcohol, about 5 weight percent hydrogenated starch hydrolysate, about 5 weight percent glycol stearate SE, about 3 weight percent avocado sterols, and about 10 weight percent borage oil.

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Another embodiment of the composition comprises about 20 weight percent polyethylene glycol 200, about 20 weight percent propylene glycol, about 20 weight percent polyethylene glycol 8,000, about 10 weight percent behenyl alcohol, about 10 weight percent stearyl alcohol, about 5 weight percent sodium PCA, about 5 weight percent glycol stearate SE, about 2 weight percent cholesterol, and about 8 weight percent borage oil.

Another embodiment of the composition comprises about 42 weight percent polyethylene 200 about 20 weight percent polyethylene glycol 8000, about 10 weight percent behenyl alcohol, about 10 weight percent stearyl alcohol, about 5 weight percent glycol stearate SE, about 3 weight percent soy sterol, and about 5 weight percent evening primrose oil.

Another embodiment of the present invention is a method for enhancing/restoring/maintaining the skin barrier function of a user. The method comprises the steps of:

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 contacting a tissue or towel product on the skin of said user wherein said material comprises a skin barrier enhancing/restoring/maintaining composition that provides a skin barrier enhancing/restoring/maintaining benefit upon transfer of the composition to the user's skin;

 transferring at least a portion of the composition during use of the tissue or towel product;

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c) repeating steps a) and b) with one or more additional tissue or towel product with sufficient frequency to enhance/restore/maintain the skin barrier in an area of skin contacted by the tissue or towel product, relative to skin contacted by an equivalent tissue or towel product that does not comprise the skin barrier enhancing/restoring/maintaining composition.

The skin barrier enhancing/restoring/maintaining composition of the method comprises from about 5 to about 90 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater, from about 1 to about 25 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 10 weight percent of humectant, from about 1 to

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about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol and sterol derivative.

The composition may have a melting point from about 30 °C. to about 100 °C. The resolidified composition may have a process viscosity greater than about 50 centipoise. The resolidified composition may have a penetration hardness of from about 5 to about 360 millimeters. The method may further comprise using a tissue or towel material having a skin-barrier enhancing/restoring/maintaining composition by the user on each use occasion. The method may further comprise using a tissue or towel material which does not comprise a skin-barrier enhancing/restoring/maintaining composition by the user intermittently. The method may further comprise using the tissue or towel material comprising a skin-barrier enhancing/restoring/maintaining composition by a user whose skin is compromised and with sufficient frequency to improve skin-barrier function.

The amount of hydrophilic solvent, including water if present, in the hydrophilic composition can be from about 10 to about 95 weight percent, more specifically from about 25 to about 75 weight percent, more specifically from about 30 to about 60 weight percent. As used herein, suitable hydrophilic solvents include, but are not limited to, the following materials: propylene glycol, low molecular weight polyethylene glycols (molecular weights of less than 720 and liquid at room temperature), methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, glycerin, sorbitol solutions, hydrogenated starch hydrolysate, and silicone glycols, water, and the like, as well as mixtures thereof.

The amount of high molecular weight polyethylene glycol in the hydrophilic composition can be from about 5 to about 95 weight percent, more specifically from about 10 to about 50 weight percent, and still more specifically from about 15 to about 25 weight percent. The high molecular weight polyethylene glycol in the hydrophilic lotion compositions of the present invention primarily functions as an immobilizing agent for the hydrophilic solvent and any active ingredient. In addition to immobilizing the solvent, and reducing its tendency to migrate, the high molecular weight polyethylene glycol in the hydrophilic lotion composition provides a tackiness to the hydrophilic lotion composition which improves the transfer to the skin of the user. As used herein, suitable high molecular weight polyethylene glycols include, but are not limited to, the following

materials: polyethylene glycols having an average molecular weight of 720 daltons or greater, and the like, as well as mixtures thereof. These materials are not liquid at room temperature. Particularly suitable high molecular weight polyethylene glycols can have an average molecular weight of from 720 to about 1,840,000 daltons, more specifically from about 1,400 to about 440,000 daltons, and still more specifically from about 1,760 to about 10,570 daltons.

The amount of fatty alcohol in the hydrophilic composition can be from about 1 to about 30 weight percent, more specifically from about 10 to about 25 weight percent, and still more specifically from about 15 to about 20 weight percent. As used herein, suitable fatty alcohols include, but not limited to, the following materials: alcohols having a carbon chain length of C_{14} - C_{30} or greater, including cetyl alcohol, stearyl alcohol, arachidyl alcohol, and behenyl alcohol, and the like, as well as mixtures thereof.

The amount of humectant in the hydrophilic composition can be from about 0.5 to about 30 weight percent, more specifically from about 1 to about 20 weight percent, and still more specifically from about 5 to about 10 weight percent. Humectants are typically cosmetic ingredients used to increase the water content of the top layers of the skin. This group of materials includes primarily hydroscopic ingredients. As used herein, suitable humectants include, but are not limited to, the following materials: Acetamide MEA, Aloe Vera Gel, Arginine PCA, Chitosan PCA, Copper PCA, Com Glycerides, Dimethyl Imidazolidinone, Fructose, Glucamine, Glucose, Glucose Glutamate, Glucuronic Acid, Glutamic Acid, Glycereth-7, Glycereth-12, Glycereth-20, Glycereth-26, Glycerin, Honey, Hydrogenated Honey, Hydrogenated Starch Hydrolysate, Hydrolyzed Com Starch, Lactamide MEA, Lactic Acid, Lactose Lysine PCA, Mannitol, Methyl Gluceth-10, Methyl Gluceth-20, PCA, PEG-2 Lactamide, PEG-10 Propylene Glycol, Polyamino Sugar Condensate, Potassium PCA, Propylene Glycol, Propylene Glycol Citrate, Saccharide Hydrolysate, Saccharide Isomerate, Sodium Aspartate, Socium Lactate, Sodium PCA, Sorbitol, TEA-Lactate, TEA-PCA, Urea, Xylitol, and the like, as well as mixtures thereof.

The amount of oil-in-water emulsifying surfactant having an HLB range greater than 7 in the hydrophilic composition can be from about 1 to about 20 weight percent, more specifically from about 2 to about 15 weight percent, and still more specifically from about 3 to about 10 weight percent. Emulsifying surfactants are employed typically in cosmetic preparations to form emulsions of various components. The immiscible phase, such as an oil, is dispersed as droplets in the continuous phase, such as water.

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The preferred surfactants include, but not limited to Emulsifying Wax NF, Glyceryl Stearate, Glyceryl Stearate SE, Glycol Stearate, Glycol Stearate SE, Glycereth-20 Stearate, Glyceryl Behenate, Glyceryl Hydroxystearate, Glyceryl Laurate SE, Glyceryl Oleate, Glyceryl Oleate SE, Propylene Glycol Oleate, Propylene Glycol Oleate SE, Propylene Glycol Stearate, Propylene Glycol Stearate, Sorbitan Stearate, Sorbitan Trioleate, and the like, as well as mixtures thereof.

The amount of a sterol or sterol derivative or mixture of sterols or sterol derivatives in the hydrophilic composition can be from about 0.1 to about 10 weight percent, more specifically from about 0.5 to about 5 weight percent, and still more specifically from about 0.8 to about 3 weight percent. As used herein, suitable β -sterols include, but are not limited to, the following materials: sterols having a tail on the 17 position and having no polar groups, for example cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, lanasterol, soy sterol, avocado sterols, sterol esters, and the like, and sourced from natural extracts (such as avocadin and lanolin, and the like), as well as mixtures thereof.

The amount of a natural fat or oil or a mixture of natural fats or oils in the hydrophilic composition can be from about 0.1 to about 30 weight percent, more specifically from about 0.5 to about 20 weight percent, and still more specifically from about 1 to about 10 weight percent. As used herein, the phrase natural fats or oils is understood to include fats, oils, essential oils, fatty acids, fatty alcohols, phopholipids, and mixtures thereof. As used herein, suitable natural fats or oils include, but are not limited to, the following materials:

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Fats and Oils: Apricot Kernel Oil, Avocado Oil, Babassu Oil, Borage Seed Oil, Butter, C12-18 Acid Triglyceride, Camellia Oil, Canola Oil, Caprylic/Capric/Lauric Triglyceride, Caprylic/Capric/Linoleic Triglyceride, Caprylic/Capric/Stearic Triglyceride, Caprylic/Capric Triglyceride, Carrot Oil, Cashew Nut Oil, Castor Oil, Cherry Pit Oil, Chia Oil, Cocoa Butter, Coconut Oil, Cod Liver Oil, Com Germ Oil, Corn Oil, Cottonseed Oil, C₁₀-C₁₈ Triglycerides, Egg Oil, Epoxidized Soybean Oil, Evening Primrose Oil, Glyceryl Triacetyl Hydroxystearate, Glyceryl Triacetyl Ricinoleate, Glycosphingolipids, Grape Seed Oil, Hazelnut Oil, Human Placental Lipids, Hybrid Safflower Oil, Hybrid Sunflower Seed Oil, Hydrogenated Castor Oil, Hydrogenated Coconut Oil, Hydrogenated Cottonseed Oil, Hydrogenated C₁₂-C₁₈ Triglycerides, Hydrogenated Fish

Oil, Hydrogenated Lard, Hydrogenated Menhaden Oil, Hydrogenated Mink Oil, Hydrogenated Orange Roughy Oil, Hydrogenated Palm Kernel Oil, Hydrogenated Palm Oil, Hydrogenated Palm Oil, Hydrogenated Shark Liver Oil, Hydrogenated Soybean Oil, Hydrogenated Tallow, Hydrogenated Vegetable Oil, Lard, Lauric/Palmitic/Oleic Triglyceride, Lesquerella Oil, Linseed Oil, Macadamia Nut Oil, Maleated Soybean Oil,

Triglyceride, Lesquerella Oil, Linseed Oil, Macadamia Nut Oil, Maleated Soybean Oil, Meadowfoam Seed Oil, Menhaden Oil, Mink Oil, Moringa Oil, Mortierella Oil, Neatsfoot Oil, Oleic/Linoleic Triglyceride, Oleic/Palmitic/Lauric/Myristic/Linoleic Triglyceride, Oleostearine, Olive Husk Oil, Olive Oil, Omental Lipids, Orange Roughy Oil, Palm Kernel Oil, Palm Oil, Peach Kernel Oil, Peanut Oil, Pengawar Djambi Oil, Pentadesma Butter,

Phospholipids, Pistachio Nut Oil, Placental Lipids, Rapeseed Oil, Rice Bran Oil, Safflower Oil, Sesame Oil, Shark Liver Oil, Shea Butter, Soybean Oil, Sphingolipids, Sunflower Seed Oil, Sweet Almond Oil, Tall Oil, Tallow, Tribehenin, Tricaprin, Tricaprylin, Triheptanoin, Trihydroxymethoxystearin, Trihydroxystearin, Triisononanoin, Triisostearin, Trilaurin, Trilinolein, Trilinolenin, Trimyristin, Trioctanoin, Triolein, Tripalmitin, Trisebacin,

Tristearin, Triundecanoin, Vegetable Oil, Walnut Oil, Wheat Bran Lipids, Wheat Germ Oil, Zadoary Oil, and the like, as well as mixtures thereof.

Fatty Acids: Arachidic Acid, Arachidonic Acid, Behenic Acid, Capric Acid, Caproic Acid, Caprolic Acid, Coconut Acid, Com Acid, Cottonseed Acid, Hydrogenated Coconut Acid, Hydrogenated Menhaden Acid, Hydrogenated Tallow Acid, Hydroxystearic Acid, Isostearic Acid, Lauric Acid, Linoleic Acid, Linolenic Acid, Linseed Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Palm Kernel Acid, Pelargonic Acid, Ricinoleic Acid, Soy Acid, Stearic Acid, Tall Oil Acid, Tallow Acid, Undecanoic Acid, Undecylenic Acid, Wheat Germ Acid, and the like, as well as mixtures thereof.

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Fatty Alcohols: Behenyl Alcohol, C₉-C₁₁ Alcohols, C₁₂-C₁₃ Alcohols, C₁₂-C₁₅ Alcohols, C₁₂-C₁₆ Alcohols, C₁₄-C₁₅ Alcohols, Caprylic Alcohol, Cetearyl Alcohol, Cetyl Alcohol, Coconut Alcohol, Decyl Alcohol, Hydrogenated Tallow Alcohol, Lauryl Alcohol, Myristyl Alcohol, Oleyl Alcohol, Palm Alcohol, Palm Kernel Alcohol, Stearyl Alcohol, Tallow Alcohol, Tridecyl Alcohol, and the like, as well as mixtures thereof.

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Essential Oils: Anise Oil, Balm Mint Oil, Basil Oil, Bee Balm Oil, Bergamot Oil, Birch Oil, Bitter Almond Oil, Bitter Orange Oil, Calendula Oil, California Nutmeg Oil, Caraway Oil, Cardamom Oil, Chamomile Oil, Cinnamon Oil, Clary Oil, Cloveleaf Oil, Clove Oil, Coriander Oil, Cypress Oil, Eucalyptus Oil, Fennel Oil, Gardenia Oil, Geranium Oil, Ginger Oil, Grapefruit Oil, Hops Oil, Hyptis Oil, Indigo Bush Oil, Jasmine Oil, Juniper Oil, Kiwi Oil,

Laurel Oil, Lavender Oil, Lemongrass Oil, Lemon Oil, Linden Oil, Lovage Oil, Mandarin Orange Oil, Matricaria Oil, Musk Rose Oil, Nutmeg Oil, Olibanum, Orange Flower Oil, Orange Oil, Patchouli Oil, Pennyroyal Oil, Peppermint Oil, Pine Oil, Pine Tar Oil, Rose Hips Oil, Rosemary Oil, Rose Oil, Rue Oil, Sage Oil, Sambucus Oil, Sandalwood Oil, Sassafras Oil, Silver Fir Oil, Spearmint Oil, Sweet Marjoram Oil, Sweet Violet Oil, Tar Oil, Tea Tree Oil, Thyme Oil, Wild Mint Oil, Yarrow Oil, Ylang Ylang Oil, and the like, as well as mixtures thereof.

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The preferred natural oils include but are not limited to: Avocado Oil, Apricot Oil,
Babassu Oil, Borage Oil, Camellia oil, Canola oil, Castor Oil, Coconut oil, Corn Oil,
Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm
Kernal Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernal Oil, Phospholipids,
Rapeseed Oil, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol,
Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Sunflower Oil, Soybean Oil and the like
and as well as mixtures thereof.

In some embodiments of the present invention, the hydrophilic composition may contain petrolatum or mineral oil. The amount of petrolatum or mineral oil in the composition can be from about 0 to about 30 weight percent, more specifically from about 0 to about 20 weight percent, and still more specifically from about 0 to about 10 weight percent.

Resolidification of the melted composition can occur almost instantaneously, without the need for external cooling means such as chill rolls, if the composition is heated to a temperature only slightly above or at the melting point of the composition. However, external means such as chill rolls, either before or after the application of melt, can be used if desired to accelerate resolidification. Such instantaneous resolidification tends to impede penetration of the composition into the tissue and retain it on the surface of the tissue, which is advantageous. For example, the temperature of the melted composition can advantageously be above the melting point about 10°C. or less, more specifically about 5°C. or less and still more specifically about 2°C. or less. As the temperature of the melted composition approaches the melting point, the viscosity of the melted composition generally increases, which further enhances the tendency of the melted composition to be retained on the surface.

For purposes herein, "melting point" is the temperature at which the majority of the melting occurs, it being recognized that melting actually occurs over a range of temperatures. The melting point of the compositions of this invention can be from about 30 °C. to about 100 °C., more specifically from about 40 °C. to about 70 °C., and still more specifically from about 50 °C. to about 60 °C.

In addition, for purposes herein, "penetration hardness" is the needle penetration in millimeters according to ASTM D 1321, "Needle Penetration of Petroleum Waxes. Lower needle penetration hardness values correspond to harder materials. The penetration hardness of the compositions of this invention can be from about 5 to 360 millimeters, more specifically from about 5 to about 200 millimeters, more specifically from about 5 to about 150 millimeters, and still more specifically from about 5 to about 100 millimeters. (Formulations having a needle penetration hardness greater than 360 millimeters cannot be measured using ASTM method D 1321).

The hardness of the formulations of this invention is important for two reasons. First, the softer the formulation the more mobile the formulation will be, making the formulation more likely to migrate to the inward facing surfaces and inner plies of the tissue, which is not desirable. Secondly, softer formulations tend to be more greasy/oily to the touch, which is also less desirable. In general, formulations having a needle penetration hardness of from about 200 to 360 millimeters feel creamy to slightly greasy with less smoothness (depending on additives). Formulations that have needle penetration hardness values of from about 5 to about 200 millimeters feel silky to creamy and very smooth (depending on additives).

The melt point viscosity and/or the process temperature viscosity of the formulations or compositions of this invention is important for two reasons: First, the higher the melt point viscosity or the process temperature viscosity as it is applied to the outside surface of the tissue or towel product, the formulation is less likely to penetrate through to the inward facing surfaces and inner plies of the tissue or towel product. The less formulation penetrate through the tissue or towel product the more there is on the surface of the liner where it can readily transfer to the wearers skin surface. Secondly, the higher the viscosity of the formulation at the above or at the melting point of the formulation, the less likely the formulation will migrate at typical or adverse storage conditions.

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In order to better enhance the benefits to consumers, additional ingredients can be used. The classes of ingredients and their corresponding benefits include, without limitation: antiacne actives (a drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads); antifoaming agents (reduce the tendency of foaming during processing); antimicrobial actives; antifungal actives; antiseptic actives; antioxidants (product integrity: to prevent oxidation of the natural ingredients or other formulation components); astringents - cosmetic (induce a tightening or tingling sensation on skin); astringent - drug (a drug product which checks oozing, discharge, or bleeding when applied to skin or mucous membrane and works by coagulating protein); biological additives (enhance the performance or consumer appeal of the product, including vitamins); colorants (impart color to the product); deodorants (reduce or eliminate unpleasant odor and protect against the formation of malodor on body surfaces); emollients (help to maintain the soft, smooth, and pliable appearance of the skin by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance); external analgesics (a topically applied drug that has a topical analgesic, anesthetic, or antipruritic effect by depressing cutaneous sensory receptors, of that has a topical counterirritant effect by stimulating cutaneous sensory receptors); film formers (to hold active ingredients on the skin by producing a continuous film on skin upon drying); fragrances (consumer appeal); humectants (increase the water content of the top layers of the skin); natural moisturizing agents (NMF) and other skin moisturizing ingredients known in the art; opacifiers (reduce the clarity or transparent appearance of the product); skin conditioning agents; skin exfoliating agents (ingredients that increase the rate of skin cell turnover such as alpha hydroxy acids and beta hydroxyacids); skin protectants (a drug product which protects injured or exposed skin or mucous membrane surface from harmful or annoying stimuli); solvents (liquids employed to dissolve components found useful in the cosmetics or drugs); sunscreens (ingredients that absorb at least 85 percent of the light in the UV range at wavelengths from 290 to 420 manometers, but transmit UV light at wavelengths longer than 420 manometers); and, surfactants (as solubilizing agents and suspending agents).

In addition, to these classes of ingredients, from about 0.01 to about 20 weight percent of oil soluble/dispersible or lipophilic materials can be easily emulsified into the formulation using anionic, amphoteric, cationic, nonionic and/or zwitterionic surfactants. Lipophilic materials without limitation include: silicones/organomodified silicones

(protection, delayed wetting, lubricity, tissue tactile softness); oils (mineral, vegetable, and animal); fatty esters and, the like. Powders to enhance lubricity, oil adsorption, provide skin protection, astringency, opacity, etc. and microencapsulated ingredients can also be dispersed into the formulation.

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The total tissue add-on of the composition can be from about 0.5 to about 40 weight percent, more specifically from about 5 to about 30 weight percent, and more specifically from about 10 to about 15 weight percent, based on the weight of the tissue. The add-on amount will depend upon the desired effect of the composition on the product attributes and the specific composition. A preferred method to uniformly apply the heated composition to the surface of the tissue web is rotogravure printing, either direct or indirect (offset), because it is a more precise printing process and offers maximum control of the composition distribution and transfer rate. However, other printing methods, but not limted to, flexographic printing, slot coating, or spraying such as WEKO, can be used.

As used herein, all recited ranges of amounts, temperatures, molecular weights and penetration hardnesses are intended to include all sub-ranges within the recited ranges, even though not specifically stated.

The compositions of the present invention may be applied to the entire outer surface(s) of the tissue or towel product or portions thereof. The compositions of the present invention may be applied non-uniformly to the outer surface of the tissue or towel product. The term "non-uniformly", as used herein, refers to the amount, pattern of distribution, thickness of the application, areas of non-coverage, or the like, for which the composition can be varied over the outer surface(s) of the tissue or towel product.

Also as used herein, a "tissue product" can be a facial tissue, bath tissue, paper towel, dinner napkin or the like. The tissue products of this invention can be one-ply, two-ply, three- ply or more. In all cases, the composition is applied to one or both outer surfaces of the product after the product has been dried. The composition can be applied after the plies are brought together or prior to bringing the plies together. The individual plies can be layered or blended (homogeneous) creped or uncreped, throughdried or wet-pressed.

Examples

The following examples are presented to provide a more detailed understanding of 605 the invention. The particular materials and parameters are exemplary and are not intended to limit the scope of the invention.

The following formulas are used in Examples 1-3:

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	Formula 1	weight percent
	Water	qs to 100%
	Glycerin	5%
	Glyceryl stearate SE	3%
615	Borage oil	1%
,	Aloe	0.3%
	Tocopherol acetate	0.3%
	Suitable pH adjuster	

620	Formula 2	weight percent
	Water	gs to 100%
	Glycerin	5%
	Glyceryl stearate SE	3%
	Borage oil	1%
625	Soy sterol	0.8%
	Aloe	0.3%
	Tocopherol acetate	0.3%
	Suitable nH adjuster	to pH 5.5

630	Formula 3	weight percent
	Water	qs to 100%
	Glycerin	5%
	Glyceryl stearate SE	3%
	Borage oil	1%
635	Soy sterol	0.8%
	Prolipid 141	1%
		ity Products, Wayne, NJ)
	Aloe	0.3%
	Toponhoral acctate	0.3%

Tocopherol acetate 0.3%

Suitable pH adjuster to pH 5.5 (PROLIPID is commercially available from International Specialty Products located in Wayne, New Jersey. PROLIPID is generally described in U.S. Patent No. 5,849,315 to Rerek et al. which issued December 15, 1998; which is herein incorporated by reference to the extent it is consistent herewith.)

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Formula 4	weight percent
Water	qs to 100%
Lipomicron NSLE,	5%
	v-en-Yvelines, France

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	Formula 5	weight percent
	Water	qs to 100%
	Glycerin	5%
	Sterol Esters	0.5%
655	Petrolatum	1%
	Avocadin	0.5%
	ProLipid 141	1%
		ecialty Products, Wayne, NJ)

660	Formula 6	weight percent
	Propylene glycol	35%
	PEG 8000	20%
	Glycerin	5%
	Behenyl Alcohol	10%
665	Stearyl Alcohol	10%
	Glyceryl Stearate SE	3%
	Sunflower oil	3%
	Soy Sterol	3%
	Dimethicone	10%
670	DC 1428	1.0%

Example 1

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<u>Lipid-enriched absorbent tissue formulations promote barrier repair as measured by</u>

<u>Transepidermal water loss (TEWL).</u>

All studies were conducted in a temperature and humidity controlled room (71° F \pm 5° F; 40 \pm 5% relative humidity).

1A. Twenty microliters of an absorbent tissue prototype formula was topically applied to the volar forearm of 24 female panelists following abrasion with emery cloth. TEWL measurements were obtained using a Dermalab evaporimeter pre- and post abrasion and 1,2, and 4 hours after application of the formulas. Mean TEWL values are expressed in Table 1.1. Repeated measures ANOVA was used to adjust for the repeated TEWL measures.

Table 1.1: TEWL (g/m²/hr) Results- Absorbent tissue formulations

	Post Abrasion Mean	1 Hour Mean	2 Hour Mean	4 Hour Mean
Formula 1	17.0	9.7 *	9.9 *	10.3
Formula 2	15.5	8.7 *	8.4 *	8.2 *
Formula 3	18.4	9.7 *	8.6 *	8.6 *
Untreated	17.4	-12.7	12.0	11.5

^{*}denotes significantly different than untreated site.

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All lipid-enriched absorbent tissue formulations repaired the skin barrier compared to the untreated site at 1,2 and 4 hours after application of the formulas as measured by TEWL.

1B. Mean TEWL values following the same study design described above are expressed in Table 1.2. The pre-abrasion (baseline) TEWL values were subtracted from all of the other readings so as to correct for underlying subject-to-subject differences. All statistical evaluations were made on these differences.

Table 1.2: TEWL (g/m²/hr) Results- Absorbent tissue formulations

	Post Abrasion Mean	1 Hour Mean	2 Hour Mean	4 Hour Mean
Formula 4	12.0	6.4*	5.6*	5.1*
Formula 5	12.3	2.7*,**	2.4*,**	2.7*,**
Untreated	11.5	9.9	9.6	10.0

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*denotes significantly different than untreated site

Both formula 4 and 5 repaired the skin barrier compared to the untreated site as measured by TEWL. In addition, Formula 5 repaired the barrier significantly better than Formula 4. Formula 4 contains Lipomicron NSLE, a Sederma (Le Perray-en-Yvelines, France) product at the recommended use level that is marketed as a product for protection of the cutaneous barrier.

710 <u>Example 2</u>

<u>Lipid-enriched absorbent tissue formulations enhance skin moisturization as measured by conductance.</u>

- 715 All studies were conducted in a temperature and humidity controlled room (71° F \pm 5° F; 40 \pm 5% relative humidity).
 - 2A. Twenty microliters of an absorbent tissue prototype was topically applied to the volar forearm. Conductance measurements were obtained using the Skicon instrument before application of the formulas and 1,2, 4, and 6 hours post application. Mean

^{**}denotes significantly different than formula 5

conductance values are expressed in Table 2.1. A pair-wise comparison for each time period using univariate ANOVAs was appplied.

Table 2.1: Conductance- Absorbent tissue formulations

10000 2.1.	01100000100				
·	Baseline	1 Hour	2 Hour	4 Hour	6 Hour
	Mean	Mean	Mean	Mean	Me <u>an</u>
Formula 1	197.7	366.5*	365.7*	349.7*	345.4*
Formula 2	182.8	298.6*	297.5*	311.5*	304.6*
Formula 3	168.2	299.1*	302.8*	296.5*	296.4*
Untreated	164.3	178.3	176.9	175.0	176.3

* denotes significantly different than untreated site.

All absorbent tissue formulas significantly enhanced skin moisturization at 1, 2, 4 and 6 hours post application of the formulas compared to the untreated site.

2B. Mean Conductance values following the same study design described above with the exception that a conductance measure was not obtained at 6 hours post application are expressed in Table 2.2. The pre-application (baseline) conductance values were subtracted from all of the other readings so as to correct for underlying subject-to-subject differences. All statistical evaluations were made on these differences.

Table 2 2: Conductance - Absorbent tissue formulations

10010 2.2.		CC 71200	100111 11000
	1 Hour	2 Hour	4 Hour
	Mean	Mean	Mean
Formula 4	50.7	40.3	39.1
Formula 5	194.0*	166.6*	142.2*
Untreated	31.7	17.3	12.3

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*denotes significantly different than untreated site.

Formula 5 significantly enhanced skin moisturization at 1, 2 and 4 hours post

application of the formulas compared to the untreated site. Formula 4 failed to enhance
skin moisturization at any of the times tested. Formula 4 contains Lipomicron NSLE,a

Sederma (Le Perray-en-Yvelines, France) product at the recommended use level that is
marketed as a product for protection of the cutaneous barrier.

745 It can be appreciated that the above example formulations can be easily incorporated into the compositions described within this invention and deliver equivalent skin health benefits.

750 Example 3

Repetitive wiping with an absorbent tissue treated with a hydrophilic lipid-enriched formula reduces barrier damage compared to an untreated absorbent tissue

Absorbent tissue treated with a hydrophilic lipid-enriched formula was repetitively wiped on the side of the face to determine the extent of barrier damage as measured by TEWL. The study consisted of repetitively wiping the face of 10 panelists with the absorbent tissues for a total of 15 wiping cycles. The wiping cycles were timed to be approximately 30 minutes apart with each wiping cycle consisting of 20 wipes. A baseline TEWL reading and TEWL readings after every two wiping cycles were obtained for each panelist using the Dermalab evaporimeter. The change in TEWL between wiping cycles was determined for each treatment.

Treatment	Estimated increase in TEWL/ wiping cycle
Absorbent tissue treated with formula 6	3.9*
Non-treated absorbent tissue	6.4

*denotes statistically different than non-treated absorbent tissue

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Repetitive wiping with the absorbent tissue treated with the lipid-enriched hydrophilic formula resulted in less skin barrier damage compared to the untreated absorbent tissue.

Thus, the Examples representatively illustrate that the hydrophilic composition of
the present invention may provide absorbent tissue products having improved softness as
well as providing improved protection of the skin barrier function. Accordingly, the
different aspects of the present invention can advantageously provide absorbent tissue
products which, when compared to conventional tissue products, are softer and have
improved protection of skin barrier function. Such absorbent tissue products can
advantageously be used for absorbent tissue products, such as facial tissue, bath tissue,
paper towels, and the like.

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While the invention has been described in detail with respect to the specific aspects thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these aspects. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.

We claim:

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1. A tissue or towel product having two outer surfaces, wherein one or both outer surfaces of the product have a hydrophilic composition that enhances skin barrier comprising:

from about 10 to about 95 weight percent hydrophilic solvent; from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater;

from about 1 to about 30 weight percent of a C_{14} to C_{30} or greater fatty alcohol; from about 0.5 to about 30 weight percent of humectant;

from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7;

from about 0.1 to about 10 weight percent sterol and sterol derivative; and, from about 0.1 to about 30 weight percent of natural fats or oils.

- 2. The product of Claim 1, wherein said composition having a melting point from about 30° C to about 100 °C.
- **3.** The product of Claim 1, wherein said composition has a penetration hardness of from about 5 millimeters to about 360 millimeters.
- **4.** The product of Claim 1, wherein the add-on amount of said composition is from about 0.5 to about 30 weight percent based on the weight of said product.
- 5. The material of Claim 1, wherein the add-on amount of said composition is from about
 0.1 grams per meter squared (g/m²) to about 30 g/m² of said material.
- 6. The product of Claim 1, wherein said hydrophilic solvent is water.
- 7. The product of Claim 1, wherein said hydrophilic solvent is propylene glycol.

8. The product of Claim 1, wherein said hydrophilic solvent is a low molecular weight polyethylene glycol.

- 9. The product of Claim 1, wherein said hydrophilic solvent is glycerin.
- **10.** The product of Claim 1, wherein said hydrophilic solvent is hydrogenated starch hydrolysate.
- 11. The product of Claim 1, wherein said fatty alcohol is cetyl alcohol.
- 12. The product of Claim 1, wherein said fatty alcohol is stearyl alcohol.
- 13. The product of Claim 1, wherein said fatty alcohol is arachidyl alcohol.
- 14. The product of Claim 1, wherein said fatty alcohol is behenyl alcohol.
- **15.** The product of Claim 1, wherein said molecular weight of said high molecular weight polyethylene glycol is from about 720 to about 1,840,000 daltons.
- **16.** The product of Claim 1, wherein said molecular weight of said high molecular weight polyethylene glycol is from about 1,400 to about 440,000 daltons.
- **17.** The material of Claim 1, wherein said high molecular weight polyethylene glycol is polyethylene glycol 1,400.
- **18.** The material of Claim 1, wherein said high molecular weight polyethylene glycol is polyethylene glycol 8,000.
- **19.** The material of Claim 1, wherein said high molecular weight polyethylene glycol is polyethylene glycol 10,000.

- 20. The material of Claim 1, wherein said humectant is glycerin.
- 21. The material of Claim 1, wherein said humectant is sorbitol.
- **22.** The material of Claim 1, wherein said humectant is hydrogenated starch hydrolysate.
- 23. The material of Claim 1, wherein said surfactant is glyceryl stearate SE.
- 24. The material of Claim 1, wherein said surfactant is glycol stearate SE.
- 25. The material of Claim 1, wherein said surfactant is emulsifying wax NF.
- 26. The material of Claim 1, wherein said sterol or sterol derivative is soy sterol.
- 27. The material of Claim 1, wherein said sterol or sterol derivative is cholesterol.
- 28. The material of Claim 1, wherein said sterol or sterol derivative is lanasterol.
- 29. The material of Claim 1, wherein said natural fat or oil is sunflower oil.
- 30. The material of Claim 1, wherein said natural fat or oil is borage oil.
- 31. The material of Claim 1, wherein said natural fat or oil is avocado oil.
- **32.** A method of making a tissue or towel product having an outer surface comprising: (a) heating a composition that enhances skin barrier comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty alcohol, a humectant, an oil-in-water emulsifying surfactant having an HLB range greater than 7, a natural fat or oil, and a

sterol or sterol derivative, to a temperature above the melting point of said composition, causing said composition to melt; (b) applying said melted composition to said outer surface of a liner or tissue material web; and (c) resolidifying said melted composition.

- **33.** The method of Claim 32, wherein said composition having a melting point of from about 30 °C to about 100 °C.
- **34.** The method of Claim 32, wherein said resolidified composition has a penetration hardness of from about 5 to about 360 millimeters.
- 35. The method of Claim 32, wherein said melted composition is applied by printing.
- **36.** A skin barrier enhancing composition comprising from about 5 to about 90 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater, from about 1 to about 25 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 10 weight percent of humectant, from about 1 to about 20 weight percent of oil-inwater emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol and sterol derivative.
- **37.** The composition of Claim 36, wherein said composition having a melting point from about 30 °C. to about 100 °C.
- **38.** The composition of Claim 36, wherein said resolidified composition has a penetration hardness of from about 5 to about 360 millimeters.
- **39.** The composition of Claim 36, wherein said hydrophilic solvent is selected from the group consisting of: water, propylene glycol, low molecular weight polyethylene glycol, glycerin, sorbitol, hydrogenated starch hydrolysate, silicone glycol, and mixtures thereof.

40. The composition of Claim 36, wherein said fatty alcohol is selected from the group consisting of: cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol, and mixtures thereof.

- **41.** The composition of Claim 36, wherein said high molecular weight polyethylene glycol is selected from the group consisting of: polyethylene glycols having a average molecular weight greater than 720 daltons.
- **42.** The composition of Claim 36, wherein said humectant is selected from the group consisting of: glycerin, propylene glycol, sorbitol, polyethylene glycol, hydrogenated starch hydrolysates, sodium PCA, potassium PCA, sodium lactate, and mixtures thereof.
- **43.** The composition of Claim 36, wherein said surfactant is selected from the group consisting of: glyceryl stearate SE, glyceryl stearate, glycol stearate SE, glycol stearate, emulsifying wax NF, and mixtures thereof.
- **44.** The composition of Claim 36, wherein said sterol or sterol derivative is selected from the group consisting of: cholesterol, sitosterol, stigmasterol, ergosterol, lanasterol, soy sterol, avocado sterols, cholesterol esters, sterol esters, as well as mixtures thereof.
- **45.** The composition of Claim 36, wherein said natural fat or oil is selected from the group consisting of: avocado oil, apricot oil, babassu oil, borage oil, camellia oil, canola oil, castor oil, coconut oil, corn oil, cottonseed oil, evening primrose oil, hydrogenated cottonseed oil, hydrogenated palm kernal oil, maleated soybean oil, meadowfoam oil, palm kernal oil, phospholipids, rapeseed oil, palmitic acid, stearic acid, linoleic acid, stearyl alcohol, lauryl alcohol, myristyl alcohol, benenyl alcohol, rose hip oil, sunflower oil, and soybean oil.
- **46.** The composition of Claim 36, wherein said amount of said hydrophilic solvent is from about 5 to about 90 weight percent.

47. The composition of Claim 36, wherein the amount of said hydrophilic solvent is from about 25 to about 75 percent.

- **48.** The composition of Claim 36, wherein the amount of said high molecular weight polyethylene glycol is from about 5 to about 95 weight percent.
- **49.** The composition of Claim 36, wherein the amount of said high molecular weight polyethylene glycol is from about 15 to about 50 weight percent.
- **50.** The composition of Claim 36, wherein the amount of said fatty alcohol is from about 1 to about 30 percent.
- **51.** The composition of Claim 36, wherein the amount of said surfactant is from about 1 to about 20 percent.
- **52.** The composition of Claim 36, wherein the amount of said sterol or sterol derivative is from about 0.1 to about 10 percent.
- **53.** The composition of Claim 36, wherein the amount of said natural fat or oil is from about 0.1 to about 30 percent.
- **54.** A method for enhancing/restoring/maintaining skin barrier function skin of a user, comprising the steps of:

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- contacting a tissue or towel product on said skin of said user wherein said product comprises a skin barrier enhancing/restoring/maintaining composition that provides a skin barrier enhancing/restoring/maintaining benefit upon transfer of said composition to said user's skin;
- b) transferring at least a portion of said composition during use of said tissue or towel product; and,
- c) repeating steps a) and b) with one or more additional tissue or towel product with sufficient frequency to enhance/restore/maintain said skin barrier in an area of skin contacted by said liner or tissue material, relative

to skin contacted by an equivalent tissue or towel product that does not comprise said skin barrier enhancing/restoring/maintaining composition, wherein said skin barrier enhancing/restoring/maintaining composition comprises: from about 5 to about 90 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater, from about 1 to about 25 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 10 weight percent of humectant, from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol and sterol derivative.

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- **55.** The method of Claim 54, wherein said composition having a melting point from about 30°C. to about 100°C.
- **56.** The method of Claim 54, wherein said resolidified composition has a process viscosity greater than about 50 centipoise.
- **57.** The method of Claim 54, wherein said resolidified composition has a penetration hardness of from about 5 to about 360 millimeters.
- **58.** The method of Claim 54, wherein said tissue or towel product comprising said skin-barrier enhancing/restoring/maintaining composition are used by said user on each use occasion.
- **59.** The method of Claim 54, wherein said tissue or towel product which do not comprise a skin-barrier enhancing/restoring/maintaining composition are used by said user intermittently.
- **60.** The method of Claim 54, wherein said tissue or towel product comprising said skin-barrier enhancing/restoring/maintaining composition are used by a user whose skin is compromised and are used with sufficient frequency to improve skin-barrier function.

INTERNATIONAL SEARCH REPORT

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Category *	Citation of document, with indication, where appropriate, of the rele	vant passages	Relevant to daim No.
	A CAMP	5.00	1 32 36
X	WO 99 13861 A (THE PROCIEK & GAMB 25 March 1999 (1999-03-25)	LE CO.)	
	page 41, line 5-14; claims 1-25;	examples	-
	1-5		
A	WO GO 12519 A (THE PROCTER & GAMB	LE CO.)	1
^	18 March 1999 (1999-03-18)		
	the whole document		
A	US 4 690 821 A (J. SMITH ET AL.)		1
]^.	1 September 1987 (1987-09-01)		
	the whole document		
A	FR 2 331 980 A (T.M. CHEN)		1
1	17 June 1977 (1977-06-17)		,
	the whole document		,
1			
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Fur	ther documents are listed in the continuation of box C.	Patent family members are listed in	n annex.
Special co	ategories of cited documents:	"T" later document published after the linter	national filing date
"A" docum	ent defining the general state of the art which is not	cited to understand the principle or the	ue approcuertos
"E" earlier	dered to be of particular relevance document but published on or after the international	invention "X" document of particular relevance; the c	aimed invention
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INTERNATIONAL SEARCH REPORT

information on patent family members

Inter mai Application No PCT/US 00/11142

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9913861	Α .	25-03-1999	AU EP ZA	8745598 A 1011630 A 9808057 A	05-04-1999 28-06-2000 17-02-1999
WO 9912519	A	18-03-1999	AU EP ZA	8642598 A 1011629 A 9807944 A	29-03-1999 28-06-2000 05-03-1999
US 4690821	Α	01-09-1987	NONE		
FR 2331980	A	17-06-1977	BE	836756 A	16-04-1976